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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,881	06/07/1999	SHOICHI OZAKI	S71761PCUS	8089

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CHRISTOPHER J. BUNTEL, PH.D.  
BAKER BOTTS L.L.P.  
910 LOUISIANA  
HOUSTON, TX 77002

EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/214,881

Applicant(s)

Ozaki et al.

Examiner

Patrick J. Nolan

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 24, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4, 6, 7, 9-14, and 16 is/are pending in the application.
- 4a) Of the above, claim(s) 7 and 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 6, 14, and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: ☐ approved ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

**Part III DETAILED ACTION**

1. Claims 4, 6-7, 9-14 and 16 are pending.
2. Claims 7 and 9-13 stand withdrawn from consideration as being directed to a non-elected invention, for reasons set forth in Paper No. 11.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4 and 14 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of human, porcine, bovine and rat HMG for the binding of autoantibodies in human SLE, Sjogrens syndrome, Behcet's disease, scleroderma, primary biliary cirrhosis, microscopic polyangitis/polyarteritis nodosa, ulcerative colitis, Crohn's disease and autoimmune hepatitis does not reasonably provide enablement for the use of any HMG-1 or HMG-2 family protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims, for reasons of record set forth in Paper No. 15.

Applicant's arguments filed 1-24-02 have been fully considered but are not found persuasive.

Applicant argues the claims are limited to antibodies from an autoimmune patient which bind to a polypeptide having 90 or 80% sequence homology to SEQ ID NOS 1 and 2 respectively.

However, the claims are being interpreted by the Examiner as broader. Claim 4 and 14 drawn to any human HMG-1 or 2 protein is considered broader than those recitations limited to only SEQ ID NOS. In fact applicant and the art only recognizes one human HMG-1 polypeptide, SEQ ID NO. 1 and only one human HMG-2 polypeptide, SEQ ID NO. 2. Furthermore as the examiner is reading the claim the limitation of the resulting antigen binding to an antibody from a person with an autoimmune disease is only directed to the fragment. It is suggested Applicant amend their claims as follows:

--A kit .... comprising: a first antigen selected from the group consisting of a polypeptide having an amino acid sequence homology of 90% or more with SEQ ID NO. 1, and a fragment of said polypeptide, wherein said polypeptide or fragment thereof specifically binds with an antibody from an autoimmune patient;

...-- , and so forth for the second part of said claim.

**The following new ground of rejection is necessitated by Applicant's amendment filed 1-24-02**

5. Claims 6 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.


It is unclear from the Applicant's specification whether or not chicken and mouse HMG-1 and HMG-2 proteins have 90 and 80% sequence homology, respectively, making the claims indefinite because they could be broader in scope than the claims they depend upon. Clarification is required.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939.

  
Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
April 7, 2002